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| STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314 | | | ASTORINO, MICHAEL C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,564

Applicant(s)

SASSE ET AL.

Examiner

Michael Astorino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/29/2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The examiner's acknowledges the applicant's response to the first office action filed March 22, 2004, wherein the applicant has amended claims 1, 3, 4, 5, 6, 8, 11, 12, 13, 14, 19, and 20, added new claim 22. Currently claims 1-22 are pending in this action.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 03/04/1999. It is noted, however, that applicant has not filed a certified copy of the Australia PP 9022 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Dempsey et al US Patent Number 6,132,371 A.

Claim 1. Apparatus for physiological monitoring of a remote subject including:

a base station having a transmission means for transmitting a reference signal

(54); and

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at least one physiological monitoring probe (20) connectable to said subject, said physiological monitoring probe or probes having:

receiver means for receiving said reference signal (58);

monitoring means for monitoring said subject and generating a condition signal containing information related to a condition or conditions of said subject (ECG electrodes);

intermediate signal means for generating an intermediate signal derived by combining said condition signal with a fixed or varying frequency sub-carrier signal before modulating said reference signal (column 6, lines 13-40);

modulation means for modulating said reference signal with said intermediate signal to produce a modulated reference signal containing said information contained in said condition signal (column 6, lines 13-40); and

passive retransmission means for passively retransmitting said modulated reference signal to said base station ("re-radiated", column 6, lines 13-40);

wherein said base station (54) has means for receiving (32, 24) said modulated reference signal, and means for demodulating (28) said modulated reference signal to obtain said information related to one or more conditions of said subject so that one or more conditions of said subject can be monitored at said base station (column 3, lines 39-67, and column 4, lines 1-59) and said base station is *operable* to vary the frequency or phase of the reference signal so that said reference signal is a spread spectrum signal. Dempsey et al.'s base station is

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“operable”, because the base station is inherently capable of performing the recited function.

Claim 2. Apparatus as claimed in claim 1, wherein said receiving means and passive retransmission means are a passive radio transponder, (“re-radiated RF signal”, column 4, lines 13-34).

Claim 3. Apparatus as claimed in claim 1, wherein said monitoring means includes a physical parameter transducer (45).

Claim 4. Apparatus as claimed in claim 1, wherein said monitoring means includes a biological electrode (ECG electrodes; 44a and 44b).

Claim 5. Apparatus as claimed in claim 1, wherein said intermediate signal means is operable to convert analog and/or digital signals (50) from the monitoring means to an intermediate signal which is used to modulate a radio frequency signal received by a passive radio transponder, so that the transponder automatically retransmits a modulated signal which contains information relating to the condition of the subject, (column 6, lines 13-61).

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Claim 6. Apparatus as claimed in claim 1, wherein said passive radio transponder uses a plurality of intermediate signals to modulate a radio frequency reference signal, (column 4, lines 13-29, and column 6, lines 13-61).

Claim 7. Apparatus as claimed in claim 1, wherein said base station includes analog and/or digital outputs for outputting data (50).

Claim 8. Apparatus as claimed in claim 1, wherein said base station is connectable to a computer network, and operable to receive input and output data via said computer network. It is inherent that a computer network exists when, “Alternatively, the signal may be processed so as to extract useful information and such information may be logged into a database at a central location”, column 4, lines 48-51.

Claim 9. Apparatus as claimed in claim 1, including encryption means so that said apparatus can transmit and/or receive data in encrypted form. It is inherent that the apparatus taught in Dempsey “can” transmit and/or receive encrypted data.

Claim 10. Apparatus as claimed in claim 1, wherein said condition signal includes a synchronous or an asynchronous data signal (inherent via transmission).

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Claim 11. Apparatus as claimed in claim 1, wherein said base station is *operable* to use either a fixed frequency reference signal or vary the frequency or phase of the reference signal by a continuously varying signal having an instantaneous value that determines the respective instantaneous frequency or phase. Dempsey et al.'s base station is "*operable*", because the base station is inherently capable of performing the recited function.

Claim 22. Apparatus as claimed in claim 1, wherein said base station is also operable to use a fixed frequency reference signal. Dempsey et al.'s base station is "*operable*", because the base station is inherently capable of performing the recited function.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 13, 14, 15, 16, 18, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dempsey et al US Patent Number 6,132,371 A in view of Martinez US Patent Number 6,639,509 B1.

Claim 13. A method of physiological monitoring of remote subject including:

- transmitting a reference signal from a base station (54) to at least one remote physiological monitoring probe (20) connected to a subject;
- monitoring said subject and generating a condition signal containing information related to a condition or conditions of a said subject (ECG);
- generating an intermediate signal derived by combining said condition signal with a fixed or varying frequency sub-carrier signal, (column 4, lines 13-29, and column 6, lines 13-61);
- modulating said reference signal with said intermediate signal to produce a modulated reference signal containing said information contained in said condition signal,;
- passively retransmitting said modulated reference signal from said biological monitoring probe to said base station, and
- demodulating said modulated reference signal to obtain said information related to the condition or conditions of said subject so that the condition or conditions of said subject can be monitored at said base station, (column 4, lines 13-29, and column 6, lines 13-61). But, Dempsey does not disclose varying the frequency or phase of said reference signal so that said reference signal is a spread spectrum reference signal. However, Martinez a reference in an analogous art discloses utilizing spread spectrum frequency hopping to avoid radio interference (column 1, lines 46-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Dempsey et al.

in view of spread spectrum reference signal of Martinez, since Martinez states the added benefit of avoid interference in the re-modulated signal.

Claim 14. A method as claimed in claim 13, wherein said intermediate signal is one of a plurality of intermediate signals, and said fixed or varying frequency sub-carrier signal is one of a plurality of sub-carrier signals, each corresponding to a respective one of said plurality of intermediate signals (column 6, lines 30-40).

Claim 15. A method as claimed in claim 13, further including converting analog and/or digital signals from a subject monitoring means to the intermediate signal which is then used to modulate a radio frequency signal received by a passive radio transponder, whereby the transponder automatically retransmits a modulated signal containing information relating to the condition of the subject, (column 4, lines 13-29, and column 6, lines 13-61).

Claim 16. A method as claimed in claim 13, including transmitting data from said base station over a computer network, and/or inputting data over a computer network (column 4, lines 44-51).

Claim 18. A method as claimed in claim 13, including transmitting said condition signal as a synchronous or an asynchronous data signal, (inherent via transmission).

Claim 19. A method as claimed in claim 13, including varying the frequency or phase of the reference signal by a continuously varying signal having an instantaneous value that determines the respective instantaneous frequency or phase, (column 4, lines 13-29 and (Martinez (column 1, lines 46-51)).

Claim 21. A method-as claimed in claim 13, wherein said method is used to monitor sleep apnoea. It is inherent that ECG is used to monitor sleep apnea.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dempsey et al US Patent Number 6,132,371 A in view of Martinez US Patent Number 6,639,509 B1 as applied to claim 13 above, and further in view of Schulze et al US Patent Number 6,443,890 B1.

Regarding claim 17, “A method as claimed in claim 13, including encrypting data to be output by said base station, and/or encrypting said modulated reference signal”, Dempsey et al disclose that the data collected maybe sent to a nurse’s station or a central location with a database but not encrypting the data. However,

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Schulze et al, a reference in an analogous art disclose encrypting data to while in route to a database (column 4, lines 55-63). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the transmission of Dempsey et in view of Martinez data in view of the encryption method of Schulze et al, since Schulze et al states in column 4, lines 61-62, encrypting data limits access so that patient privacy and confidentiality is maintained.

8. Claims 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dempsey et al US Patent Number 6,132,371 A in view of Martinez US Patent Number 6,639,509 B1 as applied to claims 1/11 and 13/19 above, and further in view of Burrows US Patent Number 5,617,871.

Regarding claims 12 and 20, dependent on claims 11 and 20, respectively, the limitation, "in which the continuously varying signal is a Pseudo-Random Binary Sequence". Martinez a reference in an analogous art discloses utilizing spread spectrum frequency hoping to avoid radio interference (column 1, lines 46-51), but does not specifically disclose using a Pseudo-Random Binary Sequence.

However, Burrows a reference in an analogous art does disclose using a Pseudo-Random Binary Sequence with a frequency modulation, (see figure 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the transmission of spread spectrum frequency modulation Dempsey in view of Martinez in view of the Pseudo-Random Binary Sequence of

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Burrows, since Burrows states in column 2, lines 60-64, spread spectrum modulation/ Pseudo-Random Binary Sequence reduces the likelihood of noise and interference, which is in concert with Dempsey in view of Martinez.

Response to Arguments

9. The applicant's arguments filed March 22, 2004 have been fully considered but they are not persuasive. In regards to claims 1-11, applicant's argument that Dempsey et al fails state "...said base station is operable to vary the frequency or phase of the reference signal so that said reference signal is a spread spectrum signal", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As stated in the rejection above the term "operable" which precedes the limitation does not patentably distinguish the claimed invention from the prior art. The same goes for claim 11, where the applicant states, "said base station is *operable* to use either a fixed frequency reference signal or vary the frequency or phase of the reference signal by a continuously varying signal having an instantaneous value that determines the respective instantaneous frequency or phase."

10. Applicant's arguments with respect to claims 12 and 20, are not persuasive. Pseudo-random binary sequence is a method of spread spectrum frequency hopping both of which are

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used to avoid radio frequency interference. The use of a passive or active sensor is immaterial, since the use of radio frequency avoidance is not exclusive to passive sensing.

11. Applicant's arguments with respect to claims 13-19 and 21 have been considered but are moot in view of the new ground(s) of rejection.

12. In response to the applicant's assertion that in claim 17, that Schulze et al. is an active sensor and the inventions would not be combined with the primary reference, it is irrelevant that the sensor is an active sensor. The present claims presents a disjunction limitation, wherein the first part references output of the base station. The first part of the disjunctive limitation does not reference any part of the passive system. Moreover, the claim as presently stated the does not require "data" to be data from a sensor, passive or active. As such, only an instance of the output of a base station must include encryption of data to be output by the base station, which Schulze et al. teaches.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Astorino whose telephone number is 703-306-9067. The examiner can normally be reached on Monday-Thursday, 10:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Astorino
July 9, 2004


MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER